



THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

Developments in Medical Law in the United Kingdom in 2005 and 2006

Citation for published version:

Gertz, R, Harmon, S, Laurie, G & Pradella, G 2006, 'Developments in Medical Law in the United Kingdom in 2005 and 2006', *European Journal of Health Law*, vol. 13, no. 2, PMID: 16958323, pp. 143-158.
<https://doi.org/10.1163/157180906777831172>

Digital Object Identifier (DOI):

[10.1163/157180906777831172](https://doi.org/10.1163/157180906777831172)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Publisher's PDF, also known as Version of record

Published In:

European Journal of Health Law

Publisher Rights Statement:

© Gertz, R., Harmon, S., Laurie, G., & Pradella, G. (2006). Developments in Medical Law in the United Kingdom in 2005 and 2006. *European Journal of Health Law*, 13(2), 143-158. 10.1163/157180906777831172

General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact openaccess@ed.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.



Developments in Medical Law in the United Kingdom in 2005 and 2006

RENATE GERTZ, SHAWN HARMON, GRAEME LAURIE
AND GEOFF PRADELLA*

Abstract

This article highlights and summarises the key developments in medical law in the jurisdictions of the United Kingdom in 2005 and to April 2006. Topics are mental health and mental capacity, data protection, freedom of information and the impact on health data, the *Human Tissue Act*, genetic research databanks, *Human Fertilisation and Embryology Act* – Review of the legislation, consultations and related case law, developments in embryo and embryonic stem cell research, clinical trials and human subject research, medical futility, and physician assisted dying.

1. Mental Health and Mental Capacity

Most patients with mental disorders seek and accept treatment voluntarily, and the proportion of these 'informal' patients has risen remarkably in the last 30 years.

* Renate Gertz is Research Fellow, Arts and Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property and Technology Law, School of Law, University of Edinburgh; Shawn Harmon is Research Fellow, INNOGEN, ESRC Centre for Social and Economic Research on Innovation in Genomics, Member of the Nova Scotia Bar, Doctoral Candidate, School of Law, University of Edinburgh; Graeme Laurie is Professor of Medical Jurisprudence, School of Law, University of Edinburgh and Co-Director of the Arts and Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property and Technology Law, School of Law, University of Edinburgh and Geoff Pradella is Research Fellow, Arts & Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property & Technology Law.

This represents a problem for incompetent voluntary patients, who can be kept in hospital for treatment deemed to be in their best interests. The English and Welsh *Mental Health Act 1983* does not provide clear limits to lawful detention and treatment in such cases, which otherwise requires that incompetent patients be, in the absence of detention, a risk to themselves or others. Voluntary patients have the freedom to discharge themselves at any time, and theoretically, therefore, do not require the protection of the courts. In reality, however, problems arise in respect of incompetent voluntary patients who may neither realise, nor be in a position to take advantage of, this freedom. A voluntarily admitted but compliant incompetent patient will not be viewed, therefore, as 'unlawfully detained' if he or she (technically) has the ability to leave of his or her own volition.

That said, informal detention has been declared contrary to Article 5(1) of the European Convention on Human Rights (see: *HL v United Kingdom* (45508/99) 81 BMLR 131), if the hospital has assumed full control over the liberty and treatment of vulnerable patients solely on the basis of clinical assessments. The recent case of *R (on the application of MH) v Secretary of State for the Department of Health*,¹ has also established that the 1983 Act is incompatible with Article 5(4) of the Convention, as it does not adequately provide for the reference of cases to the courts when patients are unable to express, or exercise their rights on their own. It is this type of situation that the provisions in the newly-enacted *Mental Capacity Act 2005*, (which comes into force in 2007) are anticipated to address, providing greater protection (by way of representation) for patients who lack the capacity to administer their own affairs. These issues, and the need for urgent reform also resulted in the initiation of a consultation by the Department of Health in 2005. Attempts to reform the *Mental Health Act 1983* have met with considerable controversy and no significant progress has been made to date.

More broadly,² the advent of the *Mental Capacity Act 2005* represents the culmination of almost a decade of attempts at legislative reform. The Act maintains the quintessentially English approach found at common law which is focused on 'best interests' but the legislation lays out a checklist of issues to be considered in determining those interests, which in turn must be read against a set of guiding principles which underpin the entire instrument. The principles impose, first and foremost, a presumption of capacity and an obligation to assist individuals to make their own decisions as far as it is practicable to do so.³ The irrational or thought-to-be-unwise decisions of *competent* persons must be respected, reflecting the

1 [2004] EWCA Civ 1609.

2 This section borrow from our recent textbook, JK Mason and GT Laurie, *Mason and McCall-Smith's Law and Medical Ethics*, Seventh Edition, Oxford University Press, 2006.

3 *Mental Capacity Act 2005*, s.1.

common law position. Where incompetence has been established, decisions taken for the person must be in their best interests and in the least restrictive manner, viz, the impact on their rights, freedoms and interests. Section 4 fleshes out the meaning of best interests. This is to be an objective test – not one based in substituted judgment – and it requires that *all* factors listed in the section be weighed in the decision-making process with none having any more importance than any other. Moreover, the incapacitated person should be an integral part of that process so far as it is possible. Consideration should also be given to the likelihood of the person recovering capacity sufficiently to be able to make the decision in the reasonably foreseeable future. The factors to be considered include: the person's past and present wishes and feelings, their beliefs and values to the extent they might influence their decisions if they had capacity, and the views of other parties interested in the incompetent's welfare (to include anyone named by the incapax, carers, any donee of a lasting power of attorney and any court-appointed deputy). The obligation, then, is to consult widely and, by implication, to gather as much relevant information as possible. Notwithstanding, 'best interests' is never defined in the Act: the task of acting within their limits thus remains one which a decision-maker must justify in each circumstance. Nor is there any explicit guidance within the Act itself on *how* balancing of factors should be done.

Section 9 provides for the appointment of Lasting Power of Attorney which includes a new power in English law, namely, the authority to consent to or refuse medical treatment on behalf of the incapacitated person. This is subject to two important riders: (i) decisions are subordinated to valid advance directives created by the person in accordance with ss. 24-26 of the Act, and (ii) the decision-making power in respect of the administration or withdrawal of life-sustaining care must be expressly provided for in the appointing instrument. Finally, a new Court of Protection⁴ will be created and would have power to declare acts, proposed acts or omissions (e.g. a failure to treat) as lawful in respect of patient's best interests; it will be assisted by the new Office of the Public Guardian.⁵

2. Data protection, freedom of information and the impact on health data

The *Freedom of Information Act 2000* and the *Freedom of Information (Scotland) Act 2002* both came into force on 1 January 2005. This freedom of information (FoI) legislation imposes obligations of transparency, openness and ease of access

⁴ *Mental Capacity Act 2005*, Part 2, having the same powers as the High Court (s.47(1)).

⁵ *Mental Capacity Act 2005*, ss.57 and 58.

to information on public bodies holding data as a matter of public record. Only 10 days later, the Scottish Health Service received the first request regarding health data, for information on incidences of childhood leukaemia by year and census ward for two postal areas. The request was refused for two main reasons: First, the combination of rare diagnosis, age group, small area and low numbers was thought to lead to too great a risk of identifiability, hence it was claimed that the information fell within the definition of 'personal data' under the *Data Protection Act 1998*,⁶ defined as data which relate to an individual who can be identified, either from one set of data or linkage of data sets.⁷ Such data are exempt from the obligations under the FoI legislation. Second, it was argued that the NHS did not 'hold' the data requested since some degree of analysis of existing datasets would be required to provide the information in the form requested. This distils into what is meant by the obligation in the legislation '...to provide advice and assistance to a person who proposes to make, or has made, a request for information to it.' Two questions are raised, namely what sort of advice and assistance must be given? and, are agencies required to analyse data upon request for information?

The most commonly recognised mechanism to avoid identifiability is anonymisation, but what counts as legally acceptable levels of anonymisation remains unclear. While the NHS argued that suitable anonymisation was not possible in this case, the Scottish Information Commissioner disagreed and ordered that the data be disclosed subject to a process of 'barnardisation', that is, adding a random selection of 0, +1 or -1 to the data to conceal the true figures.⁸ The case has been appealed to the Scottish Court of Session and it will be the first case in the UK to consider the tensions which exists between freedom of information and data protection regimes. It demonstrates the potential clash of cultures between, on the one hand, a world where the default position is non-disclosure and another where the expectation is that access should be given. In the field of healthcare and research, where sensitive data are at stake, the case has the potential to create a dangerous and onerous precedent for public authorities.

6 Implementing EC Directive 95/46/EC.

7 Ibid, Article 2(a).

8 The case involved a Mr Collie can be found here: <http://www.itspublicknowledge.info/index.htm>, delivered 15 August 2005.

3. The Human Tissue Act

The *Human Tissue Act 2004* is a very broad legislative enactment, repealing and replacing three different pieces of legislation in England and Wales – the *Human Tissue Act 1961*, the *Anatomy Act 1984* and the *Human Organ Transplants Act 1989*. Many of the substantive provisions of the *Human Tissue Act* are expected to come into force in April 2006. The Act is one of the most obvious responses to the scandals of Bristol⁹ and Alder Hey,¹⁰ and it makes consent the fundamental guiding principle of the law in respect of the removal, use and storage of human tissue and the analysis of DNA. The broad category of ‘consent’ is divided into ‘appropriate consent’ for the removal, use and storage of tissue, and ‘qualifying consent’ for the analysis of DNA. Subtle differences are made for ‘appropriate consent’, depending on whether the person from whom the material is excised is adult, child, incapacitated, living or deceased. The specific requirements for these types of consent are not laid out in the legislation. Guidance is to follow from the Human Tissue Authority, established by the Act to oversee regulation in the field. Criminal offences attach to failures to obtain the necessary consents under the Act or to comply with its other provisions. In particular, the Act creates a new offence of ‘having...any bodily material *intending* that any human DNA be analysed without qualifying consent...’¹¹ These are the only provisions of the Act also to apply to Scotland.

Consent is not required for dealings regarding public health surveillance, quality assurance and clinical audit, medical training or performance assessment. Research requires consent save in circumstances where it concerns anonymised samples/DNA and suitable ethical approval has been given.

While the Act regulates ‘relevant material’ removed from a human body – which includes any material consisting of or including human cells, with the exception of gametes, embryos outside the body and hair and nails from a living person – DNA itself is conspicuously missing from the definition. The legal status of ‘extracted DNA’ remains unclear and there is a suggestion that it does not fall within the terms of the Act. Regrettably, the Act does not provide any clarification to the question whether property rights in the body and in material removed from the body exist, save to perpetuate the unclear common law position that ‘work done’ on excised human material can give rise to property rights for the labourer.

9 Bristol Royal Infirmary Inquiry, *Learning from Bristol: the report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984 -1995*, Cm 5207, 2001. Available at: <http://www.bristol-inquiry.org.uk/>

10 Royal Liverpool Children’s Inquiry Report, 2001. Available at: <http://www.rlcinquiry.org.uk/>

11 *Human Tissue Act 2004*, s.45.

The Act also regulates live organ donation in conjunction with other removal and use of bodily material. Attempts to engage in commercial dealings with human materials are criminalised, as is the removal of transplantable material from a living person without compliance with yet-to-be-implemented regulations. Particularly stringent procedures had been in place to regulate genetically unrelated donors but the Human Tissue Act now makes no such distinction.

4. Genetic Research Databanks

UK Biobank¹² was officially launched on 13 March 2006 after a long preparatory phase where the controversial aspects of an undertaking of this size and nature were discussed.¹³ Altogether, UK Biobank intends to recruit 500,000 individuals aged between 40 and 69 to explore the gene/environment interaction in the onset of disease in later life. Healthy volunteers will donate blood and urine samples, have some standard physical measurements taken and answer lifestyle questions. They will also agree to give UK Biobank unlimited access to their medical records up to, and beyond, their death. At the same time, a similar, yet distinct, project was initiated north of the border – Generation Scotland¹⁴ – with the Scottish Family Health Study as its main component.¹⁵ While the approach of both studies is similar in terms of the level of commitment of participants, Generation Scotland takes a family-based approach to the research, hoping to recruit relatives in families with a history of common diseases affecting the Scottish population such as cancer, heart disease and stroke; as a consequence, the power of the study is significantly increased and the recruitment numbers are a mere 50,000. The ideal will be to recruit families with as many first degree relatives, ideally at least two siblings, as possible.

Both projects face the same governance issues as other biobanks worldwide. Each, however, has attempted to address the ethical, legal and social aspects of the projects in tandem with developments in the scientific protocols. Thus, UK Biobank established an Interim Advisory Group on Ethics and Governance to advise the funders (Medical Research Council, Wellcome Trust and the Department

¹² <http://www.ukbiobank.ac.uk/>

¹³ For recent critical comment, see, A. Jha, '500,000 People, A Span of Decades – and a Waste of Time and Money?', *The Guardian*, 23 February 2006, available at: <http://www.guardian.co.uk/science/story/0,,1715896,00.html>

¹⁴ <http://www.generationscotland.org/>

¹⁵ Launched on 2nd February with the support of the Scottish Executive: <http://news.bbc.co.uk/1/hi/scotland/4671078.stm>

of Health) on how best to set up the project.¹⁶ One outcome was the establishment of a permanent and independent Ethics and Governance Council to oversee UK Biobank.¹⁷ The Scottish Executive has similarly established an Advisory Board to Generation Scotland.¹⁸ This “Regulation +” approach supplements all standard ethical approval mechanisms and reflects, in part, public desires and concerns about the establishment of such projects.

Consent emerges as the most obvious problem for these types of longitudinal studies. While it has been generally accepted since the Nuremberg Trials that informed consent must be sought for research involving human beings, genetic research databanks such as UK Biobank and Generation Scotland are designed to establish resources for future research, the specific details of which remain unknown. Hence, at the time of consenting participants, researchers do not know the future directions their research might take. Broad, open-ended consent “to participate” is the basis upon which both projects proceed.

Common issues of governance, consent and privacy have led to increased attempts to find an international solution or at least to initiate collaboration on an international level. One example is the Public Population Project in Genomics Consortium, which intends to promote collaboration between researchers in the field of population genomics and to provide the international biobank community with the resources and tools to facilitate data management for improved methods of knowledge transfer and sharing.¹⁹ Neither UK Biobank nor Generation Scotland were formal members of the Consortium at the time of writing.

5. Human Fertilisation and Embryology Act – Review of the Legislation

The UK government, and the Human Fertilisation and Embryology Authority (HFEA) were engaged, for much of 2005, in a review of the legislation which governs reproductive technologies, and the HFEA itself. The HFEA identified a number of areas in the *Human Fertilisation and Embryology Act 1990* that present difficulties or challenges in the operation of the regulatory system for fertility treatment and embryo research. Inter alia, it suggested that: (1) “embryo” should be statutorily defined; (2) HFEA’s powers should be extended to facilitate clinical trials and to issue breach notices to non-complying institutions; (3) written consent

16 <http://www.ukbiobank.ac.uk/ethics/interimadvisory.php>

17 <http://www.egcukbiobank.org.uk/>

18 <http://www.scotland.gov.uk/News/Releases/2006/02/01122842>

19 <http://www.p3gconsortium.org/>

for the use of embryos should continue; (4) maximum storage periods for embryos should continue, but should be subject to extension when donated for research; (5) the 14-day limit for keeping embryos should be retained; (6) cell nuclear replacement research should be continued; (7) altering embryonic genetic structures for basic research should be permitted; (8) human-animal chimeras for research are acceptable if not implanted; (9) purposes of research should be statutorily listed; (10) the creation of embryos for treatment requires wider public debate.

More broadly, recommendations have included: that decisions relating to the use and boundaries of human reproductive technologies in treatment and research only be reached following balanced and informed debate (including provision of more public information); that the development and use of human reproductive technologies, and their regulation, continue to be the subject of legislation; and, that regulation be efficient, targeted, and able to accommodate new developments. Also highlighted is the need to strengthen public confidence in treatment and research, and professional confidence in the regulatory system, by making inspections risk-based and more focussed on treatment providers who are at risk of non-compliance. This reflected the fact that new technologies continue to raise the complex ethical, legal and social issues, a growing demand for fertility treatment, an increase in the number of clinics, and that treatment that has become more technically complex.

The drafting of a revised Act will consider the implications of the implementation of the European Tissues and Cells Directive, and proposals to bring the HFEA and the Human Tissue Authority together into a single body. New regulations to permit the use of embryos for stem cell research, and tight regulation of this area, are welcomed, as is giving Parliament greater powers to debate and amend the law in the future. An improved registration function, and relaxation of confidentiality provisions under a new Act are also being contemplated.

6. HFEA – Consultations

After a fairly quiet 2004, the HFEA was engaged in several significant consultations in 2005, including: whether selection of embryos (using pre-implantation genetic diagnosis) that are free from an inherited susceptibility to cancer should be licensed; guidance to licensed fertility clinics on taking account of the welfare of children born as a consequence of assisted conception treatments; and, the regulation of donor-assisted conception services (in response to a change in the

law such that the identity of those who donate sperm, eggs or embryos may be disclosed to their genetic offspring).²⁰

7. HFEA – Related Case Law

Two important decisions in the period under review concern the work of the HFEA. In *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority*,²¹ the appellant (Q) appealed a decision that the respondent (HFEA) had the power to authorise tissue typing in order to assist a woman in bearing a tissue-compatible child (selection of a ‘saviour sibling’). The House of Lords dismissed the appeal, holding as follows: (1) Pre-implantation genetic diagnosis and tissue typing could lawfully be authorised as activities to determine the suitability of an embryo for implantation within the terms of the 1990 Act. Parliament had not intended to confine the HFEA’s powers to unsuitability on grounds of genetic defects, and intended to leave it to the HFEA to decide whether activities such as tissue typing should be permitted. (2) The concept of ‘suitability’ included taking into account the particular wishes and needs of the mother. Tissue typing, like pre-implantation genetic diagnosis, provided information about the embryo’s characteristics which was relevant to the woman’s decision whether to carry the child or not. Once it was conceded that pre-implantation genetic diagnosis was licensable to produce not just a viable foetus but a genetically healthy child, there could be no logical basis for construing H’s power to end at that point.

In *Evans v United Kingdom*²² the applicant (E) complained to the European Court of Human Rights (having been denied an appeal to the House of Lords), *inter alia*, that the provisions of the 1990 Act, in so far as they permitted her former partner to withdraw his consent, after fertilisation of her eggs with his sperm, violated her Article 8 rights to respect for private and family life. The court held that, in adopting, in the Act, a clear and principled rule which was explained to parties to IVF treatment, and was clearly set out on the forms which they both signed (whereby the consent of either party could be withdrawn up at any stage up to the point of implantation of an embryo), the UK had not exceeded the margin of appreciation afforded to it, or upset the fair balance required under Article 8(2). Strong policy considerations underpinned the decision of Parliament to favour a clear rule, serving both legal certainty and maintaining public confidence in the law. It could not be said that the situation of male and female parties to IVF

²⁰ See generally, <http://www.hfea.gov.uk/Home>

²¹ [2005] UKHL 28.

²² [2006] All ER (D) 82 (Mar).

treatment could not be equated, or that a fair balance could only be preserved by holding a male donor to his consent. Although there was clearly a difference between the involvement of the two parties in IVF treatment, it did not follow that the Article 8 rights of a male donor would necessarily be worth less than those of the female. Importantly, an in vitro embryo has no right to life under Article 2 ECHR.

8. Developments in embryo and embryonic stem cell research (ESCR)

Stem cell science, and embryonic stem cell research (ESCR) in particular, are advancing quickly and outstripping regulatory provisions/concepts. For example, the Australian ESCR law is being reviewed this year despite being only three years old. The UK has recognised a need for a flexible approach to ESCR governance and its “enabling and consistent” approach is widely acclaimed. In the last year there have been several developments, both domestically and internationally, which impact on this field of research.

Domestically, the UK Stem Cell Initiative issued a Report and Recommendations in November 2005,²³ which notes that funding for ESCR which translates into clinical applications is weak,²⁴ and recommends that the HFEA, Human Tissue Authority, Medicine and Healthcare Products Regulatory Agency and Department of Health liaise closely with the biotech and healthcare industries to ensure that regulation (particularly from the EU) facilitates rather than hinders developments and treatments in this field.²⁵ Moreover, it endorses the idea of a specialist Research Ethics Committee for ESCR.²⁶

Internationally, the UN adopted a non-binding Declaration on Human Cloning, which calls on states to ban all forms of cloning and genetic engineering which is contrary to human dignity and the protection of life. In 2006, the International Consortium on Stem Cells, Ethics and Law, issued a draft Consensus Statement which suggested an international framework for ESCR, the highlights of which are: *Researchers*: ESC researchers should minimise risk of harm according to ethical norms and conduct research so as to protect the well-being and rights of donors and participants, who must provide valid informed consent. Researchers should submit (1) ESC lines to national or international depositories that subscribe

²³ <http://www.advisorybodies.doh.gov.uk/uksci/>

²⁴ Ibid, p.52.

²⁵ Ibid, p.88.

²⁶ Ibid, p.89.

to accepted standards of quality and make them publicly available, and (2) statements of ethical conduct and other documents to a public database. *Regulators*: National and international laws should be clear and flexible, so as to accommodate rapid scientific advance. Where laws restrict ESCR but not international collaborations, they should neither discriminate against nor restrict the freedom of researchers who travel to pursue ESCR in other jurisdictions, and they should not be subject to sanction upon their return. *Journals*: Editors should (1) encourage authors to provide explicit descriptions of their individual roles and potential conflicts, (2) require statements that research conforms to local laws/policies and has been approved by appropriate oversight bodies (together with copies of approved protocols, consent forms, information forms and other ethically-related documents), (3) require that ESC sources be clearly specified, and (4) promote high standards for peer review (ie: authors should submit data verifying ESC line authenticity and explanations of how they complied with accepted standards of good cell culture practice). *Stakeholders*: Steps should be taken (by regulators and civil society) to develop international ethical standards/practices in ESCR. Many of the ethical issues raised by ESCR can be addressed through existing international guidelines governing human subjects. However, new ethical challenges will arise which cannot be addressed by existing instruments (eg: gametes derived from ESC, human/non-human chimeras) so international efforts to address them must be initiated to ensure science proceeds in an ethically acceptable fashion and reduce the likelihood that diversity will result in obstacles.

9. Clinical trials and human subject research

Human Subject Research (HSR) is often described as translational research in that it shifts innovation from the academic/lab setting into medical practice. Although an absolutely vital element of healthcare development, it is also a dangerous and potentially damaging endeavour which relies on trust and altruism (often involving people in particularly vulnerable positions). This was dramatically evidenced this year by tragic gene therapy trials in the US,²⁷ and France,²⁸ and the recent and

27 BioNews, "Gene Therapy Researchers Fined Over Trial Participant's Death", February 11, 2005, at www.bionews.org.uk/new.lasso?storyid=2444 (Mar. 24/05). See also A. Chaudhuri, "Lessons from Clinical Trials from Natalizumab in Multiple Sclerosis" (2006) 332 B.M.J. 416-419, who notes the development in two patients of multifocal leucoencephalopathy after administration of a trial drug that had been subject to earlier unpublished (and non-peer reviewed) trials.

28 BioNews, "Gene Therapy Trials Under Review Following Third Cancer Case", March 7, 2005, at www.bionews.org.uk/new.lasso?storyid=2473 (Mar. 24/05).

horrifically failed trial of TGN1412 by TeGenero and Parexel in the UK, which is now being investigated and is the subject of debates about the power of consent and exemption forms and the availability of compensation.²⁹ Public confidence has further been eroded by revelations of data fabrication.³⁰ HSR governance in the UK has been overhauled in recent years, inter alia, in light of the Clinical Trials Directive, 2001/23/EC, and the Good Clinical Practice Directive, 2005/28/EC, the former which was implemented in the UK by the *Medicines for Human Use (Clinical Trials) Regulations 2004*. The latter has not yet been implemented, but amendments to the 2004 Regulations are being discussed in an effort to bring it and its terminology in line.³¹ The Directives were intended to improve the protection of patients and the reliability of research reporting and to harmonise practices throughout Europe. Unfortunately, they are widely criticised as too complex, bureaucratic, and time/finance-consuming, and thereby stifling research and hindering access to new treatments.³² In addition, they have been interpreted differently across jurisdictions, with the result that they have also failed in their harmonisation role. The sheer volume of domestic and international instruments applicable to HSR further contributes to the complexity of this area.³³

29 See E. Fennell, "Dark Days Again for Drug Trials", March 21, 2006, at www.timesonline.co.uk/article/0,200-2091840,00.html (Mar. 24/06).

30 See S. Al-Marzouki *et al.*, "Are These Data Real? Statistical Methods for the Detection of Data Fabrication in Clinical Trials" (2005) 331 B.M.J. 267-270.

31 See www.gcptraining.org.uk/files/doc/eu_directive_2005-28-ec-summary_of_proposed_changes.pdf (Mar. 24/06).

32 See A. Hemminki, "Harmful Impact of EU Clinical Trials Directive: Academic Clinical Research in Cancer Seems to Have No Future in Europe" (2006) 332 B.M.J. 501-501, M. Watson, "Harmful Impact of EU Clinical Trials Directive" (2006) 332 B.M.J. 666a, D. Hanning, "Harmful Impact of EU Clinical Trials Directive: Trial of Alerting Drug in Fibromyalgia has had to be Abandoned" (2006) 332 B.M.J. 666, C. Mitchell, "Harmful Impact of EU Clinical Trials Directive: Paediatric Oncology is Being Scuppered" (2006) 332 B.M.J. 666b.

33 Domestically, see the COREC Guidelines for Researchers on Patient Information Sheets and Consent Forms (2005), the GTAC Operational Procedures for Gene Therapy Clinical Trials (2005), the DoH Research Governance Framework for Health and Social Care (2005), the MRC Guidelines on Good Research Practice (2005), and the Wellcome Trust Guidelines on Good Research Practice (2005). Internationally, see the ICH Tripartite Guideline for Good Clinical Practice (1996), the WMA Declaration of Helsinki (2000), the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), and the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research (2005). And it has been pointed out that these overlapping instruments are sometimes in tension with one another: see S. Edwards & M. McNamee, "Ethical Concerns Regarding Guidelines for the Conduct of Clinical Research on Children" (2005) 31 J.M.E. 351-354.

With respect to the international scene, of interest is the ICMJE Policy Statement (2004), which took effect in July 2005.³⁴ It condemns selective reporting of clinical trials (ie: burying trials which reflect unfavourably on a sponsor's product), which has the effect of distorting evidence about products and undermining clinical decision-making. Under the policy, ICMJE members will only publish reports on trials that have been registered in a registry that is: (1) open to all registrants; (2) accessible for free by the public; (3) managed by a not-for-profit organisation; and (4) contains a mechanism to ensure validity of data. The information which must be registered includes: (1) a unique identifying number; (2) a statement of intervention(s) and comparison(s) being studied; (3) a statement of hypotheses; (4) definitions of outcome measures; (5) eligibility criteria and number of target subjects; (5) key dates; (6) funding source; and (7) principal investigator. They encourage non-member editors to adopt a similar policy.

10. Medical Futility

The UK courts have been called upon to consider various aspects of the law as it relates to assessments of medical futility and the impact on patient rights. The English Court of Appeal heard the controversial case of *R (On the application of Burke) v General Medical Council* in July 2005³⁵ in which Mr Burke challenged the legality of the General Medical Council's guidance to doctors concerning withholding and withdrawing life sustaining treatment.³⁶ Mr Burke suffers from spino-cerebellar ataxia, a neurological condition which entails a progressive and untreatable loss of muscle power and co-ordination but no attendant loss of mental ability, leaving the patient fully aware of the final, potentially degrading, stages of the terminal illness. Mr Burke sought assurances that he would continue to receive artificial nutrition and hydration (ANH) until he died of natural causes and that at no point could this be withdrawn. The GMC guidance indicated that doctors were not obliged to provide ANH against their clinical judgment. Munby J delivered a ruling at first instance which seemed to

³⁴ ICMJE, "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors" (2004) 351 N.E.M.J. 1250-1251. In response, see R. Krall & F. Rockhold, "More on Compulsory Registration of Clinical Trials: CSK Has Created Useful Register" (2005) 330 B.M.J. 479-480, and M. Bonati & C. Pandolfini, "More on Compulsory Registration of Clinical Trials: Complete Clinical Trial Register is Already a Reality for Paediatrics" (2005) 330 B.M.J. 480.

³⁵ [2006] QB 273.

³⁶ GMC, *Withholding and Withdrawing Life-prolonging Treatments: Good Practice in Decision-Making* (2002)

indicate that patients could claim a right *to* treatment based on their right to respect for autonomy and protection of their dignity,³⁷ with little regard to the resource consequences that such a precedent would have.³⁸ This was firmly struck down by the Court of Appeal which found for the GMC and held that: ‘...where life depended upon the continued provision of ANH there could be no question of the supply of ANH not being clinically indicated unless a clinical decision had been taken that the life in question should come to an end. That was not a decision that could lawfully be taken in the case of a competent patient who expressed the wish to remain alive.’³⁹ The case is, however, on further appeal, doubtless for the uncertainty that this ruling leaves with respect to the rights of patients who are, or become, incompetent.

It was thought that the legal position concerning the withdrawal or withholding of medical care from handicapped neonates was established in the early 1990s in the Court of Appeal when it held that clinical assessments of a child’s best interests were determinative of the lawfulness of decisions to cease or not to begin treatment.⁴⁰ Doctors would not be required to treat against their good faith clinical judgment. But a recent series of cases has revisited the position with uncertain results. Two cases in 2004 initially re-iterated the validity of the best interests test as the relevant criterion on which such decisions should be taken, but confirmed that the courts are the ultimate arbiters on such matters in cases of dispute.⁴¹ Notwithstanding, the medical assessments of futility were upheld. But in one of these cases the parents have returned to the courts on several occasions with the wavering state of their child’s health. In the process, the Court of Appeal has confirmed the legal position:

The judge must decide what is in the child’s best interests. In making that decision, the welfare of the child is paramount, and the judge must look at the question from the assumed point of view of the patient ... [t]here is a strong presumption in favour of a course of action which will prolong life, but that presumption is not irrebuttable ... [t]he term ‘best interests’ encompasses medical, emotional, and all other welfare issues ... [t]he court must conduct a balancing exercise in which all the relevant factors are weighed ... we agree

³⁷ *R (On the application of Burke) v General Medical Council* [2004] EWCA 1879, (2004) 79 BMLR 126

³⁸ See JK Mason and GT Laurie, ‘Personal Autonomy and the Right to Treatment: A Note on *R (On the application of Burke) v General Medical Council*’ (2005) 9 *Edinburgh Law Review* 123-132.

³⁹ [2005] EWCA 1003, para 53.

⁴⁰ *Re J (a minor) (wardship: medical treatment)* [1990] 3 All ER 930 and *Re J (a minor) (wardship: medical treatment)* [1992] 4 All ER 614.

⁴¹ *Re Wyatt (a child)(medical treatment: parents’ consent)* [2004] Fam Law 966 and *Re Winston-Jones (a child)(medical treatment: parents’ consent)* [2004] All ER (D) 313.

with Hedley J that whilst “intolerable to the child” should not be seen either as a gloss on or a supplementary guide to best interests, it is, as he said, a valuable guide in the search for best interests in this kind of case.⁴²

Hedley J most recently ruled on this case for an unprecedented fifth time, holding that the medical decision to refrain from intervention would be in the child’s best interests.⁴³

Latterly, however, the case of *Re MB* has been reported in *The Times*,⁴⁴ wherein the court rejected medical evidence of the intolerability of a child’s life living with the painful condition of spinal muscular atrophy and the assessment that it would be in his best interests to be allowed to die. The parental objections held sway, and this, together with the other recent developments, would indicate that the courts have in practice moved quite considerably from their deference to medical opinion in the 1990s. The effect of such a ruling is that doctors *will* now be expected to treat against their better clinical judgments.

11. Physician Assisted Dying

The Assisted Dying for the Terminally Ill Bill is currently before the House of Lords (April 2006). This initiative arose when Lord Joffe introduced a version of the Bill in 2003 and again in 2004 but progress was halted by the 2005 general election. Notwithstanding, a House of Lords Select Committee reported on the matter in April 2005 and recommended that a new Bill be introduced.⁴⁵ The current version appeared before the House in November 2005 and its salient features are that: It would make assistance in dying lawful on the fulfilment of certain conditions, being: written request from patient to be assisted to die; a suitable assessment by the attending physician of the capacity of the patient, of the terminal nature of the patient’s condition and of the patient’s unbearable suffering from the illness; the provision of adequate information and counselling, particularly about alternatives and palliative care by the attending physician who must then be satisfied of the informed and voluntary nature of the patient’s choice; attendance by a palliative care specialist; referral to a consulting physician who

⁴² *Re Wyatt (a child) (medical treatment: continuation of order)* [2005] EWCA Civ 1181, paras 85-91, 86 BMLR 173.

⁴³ *Re Wyatt* [2006] EWHC 319 (Fam).

⁴⁴ L. Smith, ‘Dying, Paralysed and in Pain, but his Short Life is Judged Worth Prolonging’, *The Times*, 16 March 2006, p.4.

⁴⁵ Select Committee on the Assisted Dying for the Terminally Ill Bill, *Assisted Dying for the Terminally Ill Bill – First Report* (2005).

must confirm the diagnosis and prognosis and repeat many of the above procedures on testing capacity, informedness, voluntariness, and “unbearable suffering” from the terminal illness; the patient must make a declaration (which is revocable) of his/her wish to die (which must be witnessed by two individuals, one of whom is a solicitor or notary public).

No assistance in dying can be given within 14 days of the date when the patient first informed the attending physician of his wish to be helped to die. The patient must confirm their declaration before any assistance takes place. The Bill contains a conscience clause for health care professionals who are not under any obligation to refer the patient to a willing colleague. This Bill addresses some of the concerns of the Select Committee, the exclusion of a referral obligation being one of them, and it also now attempts to define terms that were indistinct in earlier versions such as “terminally ill” and “unbearable suffering”.⁴⁶ The Bill fails, however, to make provision to assist those who cannot administer medication themselves, such as Dianne Pretty, whose plight before the English courts⁴⁷ was ultimately played out, and lost, before the European Court of Human Rights.⁴⁸ At most, the Bill talks of assistance “...in the case of a patient for whom it is impossible or inappropriate orally to ingest that medication, by prescribing and providing such means of self-administration of that medication, as will enable the patient to end his own life”.⁴⁹ The 2004 version of the Bill allowed direct assistance in administering medication. Now, the doctor’s role is reduced to writing a prescription and leaving the patient to self-administer.⁵⁰

46 “Terminal Illness” means an illness which in the opinion of both the attending and the consulting physician – (a) is inevitably progressive, (b) cannot be reversed by treatment (although treatment may be successful in relieving symptoms temporarily), and (c) will be likely to result in the patient’s death within six months. “Unbearable suffering” means suffering whether by reason of pain, distress or otherwise which the patient finds so severe as to be unacceptable: cl.13 of the Bill.

47 *R (on the application of Pretty) v DPP* [2002] 1 All ER 1.

48 *Pretty v UK* [2002] 35 EHRR 1.

49 Clause 1.

50 The Bill was being read in Parliament as we went to press and was eventually defeated on 12 May 2006 by 148-100 votes, the closest ever Parliamentary vote on the issue.